this section is not applicable to the device that is the subject of the HDE, and omits any such information from its HDE, the applicant shall submit a statement that identifies and justifies the omission. The statement shall be submitted as a separate section in the HDE and identified in the table of contents. If the justification for the omission is not accepted by the agency, FDA will so notify the applicant.

(e) *Address for submissions and correspondence.* Copies of all original HDE's, amendments, supplements, and requests for extension, as well as any correspondence relating to an HDE, shall be sent or delivered to the Document Mail Center (HFZ–401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, §814.104 was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§814.106 HDE amendments and resubmitted HDE's.

An HDE or HDE supplement may be amended or resubmitted upon an applicant's own initiative, or at the request of FDA, for the same reasons and in the same manner as prescribed for PMA's in §814.37. The timeframes and extension of review times set forth in §814.37 for PMA's shall also be applicable to HDE's.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, §814.106 was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§814.108 Supplemental applications.

After FDA approval of an original HDE, an applicant shall submit supplements in accordance with the requirements for PMA's under §814.39, except that a request for a new indication for use of a HUD shall comply with the requirements set forth in §814.110.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, §814.108 was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§814.110 New indications for use.

(a) An applicant seeking a new indication for use of a HUD approved under this subpart H shall obtain a new designation of HUD status in accordance with §814.102 and shall submit an original HDE in accordance with §814.104.

(b) An application for a new indication for use made under §814.104 may incorporate by reference any information or data previously submitted to the agency under an HDE.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in §814.110, paragraph (a) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§814.112 Filing an HDE.

(a) The filing of an HDE means that FDA has made a threshold determination that the application is sufficiently complete to permit substantive review. Within 45 days from the date an HDE is received by FDA, the agency will notify the applicant whether the application has been filed. FDA may refuse to file an HDE if any of the following applies:

(1) The application is incomplete because it does not on its face contain all the information required under §814.104(c);

(2) FDA determines that there is a comparable device available (other than another HUD approved under this subpart or a device under an approved IDE) to treat or diagnose the disease or condition for which approval of the HUD is being sought; or

(3) The application contains an untrue statement of material fact or omits material information.

(b) The provisions contained in §814.42(b), (c), and (d) regarding notification of filing decisions, filing dates, the start of the 180-day review period, and applicant's options in response to FDA refuse to file decisions shall apply to HDE's submitted under this subpart as well as to PMA's submitted under §814.20.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in §814.112, paragraph (b) was stayed.